PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of

Gerhardus HAAK et al.

Application No.: 09/914,794 Examiner: S. SIEFKE

Filed: September 5, 2001 Docket No.: 110510

For: SOLID PHASE EXTRACTION INSTRUMENT AND METHOD FOR SOLID PHASE EXTRACTION

BRIEF ON APPEAL

Appeal from Group 1743

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I. REAL PARTY IN INTEREST

The real party in interest for this appeal and the present application is Spark Holland B.V., by way of an Assignment recorded in the U.S. Patent and Trademark Office at Reel 012260, Frame 0545.

II. RELATED APPEALS AND INTERFERENCES

There was a prior Appeal Brief filed on October 17, 2005. In response to the Appeal Brief, prosecution of the application was reopened by the Examiner and a subsequent Office Action was mailed on January 12, 2006. The Board thus never rendered an opinion on the issues in the prior Appeal Brief.

There are no other prior or pending appeals, interferences or judicial proceedings, known to Appellants, Appellants' representative, or the Assignee, that may be related to, or which will directly affect or be directly affected by or have a bearing upon the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1 and 3-7 are on appeal.

Claims 1 and 3-30 are pending.

Claims 1 and 3-7 are rejected.

Claims 8-30 are withdrawn from consideration.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to final rejection. All claim amendments prior to final rejection have been entered and the claims in Appendix A hereto reflect entry of those amendments.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 relates to a method for solid phase extraction for analytical processes and preparation of samples. See page 1, lines 14-17 of the specification. Claims 1 and 3-7 are particularly directed to a solid phase extraction process for extracting an analyte from a sample. The various steps of the solid phase extraction outlined in claim 1 are not all always employed in the claimed method; thus, claim 1 recites that one or more of steps a) to d) are employed in the process.

With specific reference to the claims, independent Claim 1 is directed to a solid phase extraction process for extracting an analyte from a sample (see page 1, lines 14-17 of the specification) comprising one or more of a) conditioning a sorbent in a cartridge by passing a liquid suitable for conditioning through the cartridge (see page 1, lines 20 and 21 and page 22, lines 5-8 of the specification); b) applying a sample that contains the analyte to the sorbent by passing a liquid which contains the sample through the cartridge (see page 1, lines 22 and 23 and page 22, lines 9-12 of the specification); c) washing the sorbent by passing a wash liquid through the cartridge (see page 1, line 24 and page 22, lines 13-15 of the specification); and d) eluting the analyte from the sorbent by passing an elution liquid through the cartridge (see page 1, lines 25 and 26 and page 22, lines 16-18 of the specification), wherein the temperature of the cartridge is raised or lowered to a predetermined value during one or more of the steps a) to d) (see page 2, lines 20-22 of the specification), and wherein the temperature of the cartridge is raised or lowered by heating or cooling one or more of the liquids used in step a) to d) before feeding to the cartridge (see page 2, lines 25-31 of the specification).

The entire solid phase extraction procedure can be carried out at a predetermined and controlled temperature. The temperature control makes it possible to reduce the amount of solvent used and the process time. See page 2, lines 15-19 of the specification. The temperature of the cartridge is controlled by heating or cooling the liquids used in the process

prior to feeding the liquid to the cartridge 11. See page 2, lines 20-22 of the specification. Thus, not only is the temperature of the liquid controlled, the temperature of the cartridge 11 itself is also controlled. See page 2, lines 25 and 26 of the specification.

As the temperature of the cartridge 11 is controlled by controlling the temperature of the liquid, the temperature of the sorbent 13 in the cartridge 11 is similarly controlled. See page 2, lines 20 and 21 of the specification. The temperature control may be employed with the liquid for conditioning of the sorbent 13, the liquid that contains the sample, the wash liquid and/or the elution liquid. See page 2, lines 22-24 of the specification.

Such a process for cartridge temperature control in solid phase extraction provides a variety of benefits and advantages. For example, a change in temperature can take place relatively rapidly, both when heating the liquid is concerned and when cooling has to be carried out between two steps. See page 2, lines 27-29 of the specification. Another advantage is that the heating means can be constructed with a relatively small volume. See page 2, lines 29-31 of the specification. Further, if the elution liquid is heated prior to feeding it to the cartridge, then the desorption of the analyte will be accelerated. The analyte is thus desorbed into a smaller volume. See page 2, lines 32-33 of the specification. Control of the temperature also has an effect on the efficiency of the extraction (recovery). Temperature changes influence breakthrough volume. Thus, a controlled temperature increases the precision and reproducibility of the extraction. See page 3, lines 3-7 of the specification.

Fig. 1 illustrates a diagrammatic and perspective view of an solid phase extraction (SPE) instrument 1. See page 15, lines 1-4 of the specification. A cartridge holder 3 can be seen on the left- and the right-hand side of the open front. See page 15, lines 6 and 7 of the specification.

Fig. 1a shows that each of these cartridge holders essentially comprises two clamping heads 4 and 5, of which clamping head 4 is fixed and clamping head 5 is mounted such that it is

movable by means of cheeks 7 over clamping head guides 6. See page 15, lines 7-10 of the specification. The feed channels of the lines 9 and 10 continue in the clamping heads 4 and 5 and emerge in the front faces of the clamping heads 4 and 5, which front faces face one another. See page 15, lines 13-15 of the specification. When the cartridge 11 is in the clamped position, liquid can be supplied via line 9, fed through cartridge 11 and discharged via line 10, or conversely, supplied via line 10, fed through the cartridge 11 and discharged via a line 9. See page 15, lines 23-26 of the specification.

Fig. 4 illustrates a line system of the SPE instrument according to Fig. 1. See page 14, line 15 of the specification. When multi-way valve 70 is switched over, solvent supplied via line 69, or optionally sample liquid supplied via line 69, will be fed via line 72 and heating/cooling means 73 to the cartridge holder 3, passed through the cartridge 11, returned to the multi-way valve 70 via line 74 and discharged via line 71. See page 21, lines 25-28 of the specification. The heating/cooling means 73 can be used to heat or, respectively, to cool the solvent before it is passed through the sorbent. See page 23, lines 1 and 2.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

1) Claims 1 and 3-7 are rejected as allegedly being obvious under 35 U.S.C. §103(a) over U.S. Patent No. 5,512,168 (hereinafter "Fetner") in view of U.S. Patent No. 4,451,374 (hereinafter "Peterson").

VII. ARGUMENT

A. Claims 1 and 3-7 Would Not Have Been Obvious Over Fetner in View of Peterson

Claims 1 and 3-7 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Fetner in view of Peterson. According to the Examiner, the difference between claim 1 and Fetner is that the method of Fetner does not teach or suggest raising or lowering the temperature of the cartridge by flowing a heated or cooled liquid through the cartridge. The Examiner alleges that Peterson teaches a liquid chromatographic method that comprises heating the reagent solution by suitable temperature control means, i.e., a temperature control plate, which heats the reagent solution. The Examiner further alleges that it would have been obvious to one skilled in the art to heat a sample prior to passing the sample through a cartridge because sample uptake on the sorbent would be increased with the sample temperature. Moreover, the Examiner alleges that it would have been obvious to one skilled in the art to recognize that if a sample is heated and then passed through a cartridge, the cartridge temperature will increase to the temperature of the liquid that is passing therethrough. Appellants strenuously disagree with these allegations.

1. Fetner and Peterson, Taken Singly or In Combination, Do Not Teach or Suggest Raising or Lowering the Temperature of the Cartridge by Passing Heated or Cooled Liquid Through the Cartridge to Control the Temperature of the Cartridge

a. Neither Fetner nor Peterson Teach or Suggest a Required Step

Appellants submit that Fetner and Peterson, taken singly or in combination, do not teach or suggest, in any manner, heating or cooling one or more of the liquids used in steps a) to d) before feeding to the cartridge so as to adjust the temperature of the cartridge as recited in claim 1. Nowhere does Fetner and Peterson, taken singly or in combination, teach or suggest passing a heated or cooled liquid through a cartridge to raise or lower, respectively, the temperature of the cartridge.

Fetner teaches a solid phase extraction elution device that purifies one or more solutes from a contaminated solution, the purified solutes then being recovered as a concentrated solution suitable for analysis. See the Abstract of Fetner. The Examiner admits that Fetner does not teach raising or lowering the temperature of the cartridge by flowing a heated or cooled liquid through the cartridge as required in claim 1. The Examiner thus relied upon Peterson as allegedly teaching this feature of claim 1.

Contrary to the assertions of the Examiner, Peterson does not remedy the deficiencies of Fetner. In particular, Peterson also fails to teach or suggest changing the temperature of a cartridge by heating or cooling one or more of the liquids of steps a) to d) of the recited steps before feeding such liquid into the cartridge as recited in claim 1.

Peterson teaches a chromatographic column 10 through which a sample is eluted. See column 8, lines 15-20 of Peterson. The component species of the sample in Peterson ultimately appear chromatographically displaced in the chromatographic column effluent, which is delivered to the reagent addition device or post-column reactor 24. See column 8, lines 21-31 of Peterson. In the reagent addition device or post-column reactor 24, the reagent solution is maintained at a controlled temperature by suitable temperature control means. See column 8, lines 36-41 of Peterson.

In the rejection, the Examiner equates the chromatographic column 10 of Peterson to the cartridge recited in claim 1, and equates maintaining the reagent solution in the reagent addition device or post-column reactor 24 at a controlled temperature by suitable temperature control means in Peterson to raising or lowering the temperature of the cartridge by flowing a heated or cooled liquid through the cartridge as recited in claim 1. However, maintaining the reagent solution in the reagent addition device or post-column reactor at a controlled temperature by suitable temperature control means in Peterson does not teach or suggest, in

any manner, raising or lowering the temperature of the cartridge by flowing a heated or cooled liquid through the cartridge.

Peterson teaches that the reagent solution is only used after compounds are eluted from the column to chemically modify the compounds. Specifically, Peterson teaches that optionally, both or either the reagent solution or delay coil is maintained at a controlled temperature by suitable temperature control means, most simply, a temperature controlled plate which heats solution or fluid in which the delay coil is immersed and/or which heats the reagent solution. See column 8, lines 36-41 of Peterson. Additionally, Peterson teaches that the delay coil is ultimately followed by a detector 26 of a type suited for liquid chromatography. See Fig. 1 and column 8, lines 41-43. As shown in Fig. 1 of Peterson, the post-column reactor 24 is downstream with respect to the column 10 (alleged cartridge) and only provides heat to the reaction mixture after the reaction mixture passes through the column 10.

Thus, the heated reagent solution of Peterson only contacts the effluent (reaction mixture) coming <u>from</u> the column (alleged cartridge) and into the detector, fails to flow through the column, and is not capable of controlling or changing a temperature of the column. Because the heated reagent solution and the heated effluent (reaction mixture) do not flow through the column or even contact the column, the heated reagent solution and the heated effluent (reaction mixture) of Peterson are incapable of raising or lowering the temperature of the column in Peterson.

The liquid in the present claims is heated or cooled before feeding the liquid to the cartridge in order to raise or lower the temperature of the cartridge. Peterson teaches heating the reagent solution to heat the reaction delay loop and provide elevated temperatures for the effluent (reaction mixture) downstream from the column (alleged cartridge) to add residence time or reaction time for slow reaction mixtures. See column 7, lines 38-41 and Example 4 of

Peterson. Heating the reagent solution and/or reaction delay loop to provide elevated temperatures to add residence time or reaction time for slow reacting mixtures does not teach or suggest, in any manner, heating or cooling a liquid before feeding the liquid to the cartridge in order to raise or lower the temperature of the cartridge.

The effluent (reaction mixture) or the heated reagent solution in Peterson is thus only fed into the detector 26 and never fed into or in contact with the column 10 (alleged cartridge) in such a way that is capable of raising or lowering the temperature of the column 10 as alleged by the Examiner. In other words, the temperature of the column 10 (alleged cartridge) is <u>incapable</u> of being controlled by or changed by the temperature of the heated reaction mixture or reagent solution because the heated reaction mixture or reagent solution does not contact and never passes through the cartridge in a way so as to raise or lower the temperature of the cartridge as by claim 1.

Thus, Peterson also does not teach or suggest controlling the temperature of the cartridge by passing heated or cooled liquids of one or more of steps a) to d) through the cartridge, and thus cannot remedy deficiencies of Fetner in this regard.

For all the foregoing reasons, Appellants submit that even if the teachings of Fetner and Peterson were to have been combined as alleged by the Examiner, the solid phase extraction process recited in claim 1 would not have been achieved. Particularly, neither Fetner nor Peterson teaches or suggests controlling the temperature of the cartridge by heating or cooling one or more of the liquids used in the recited steps a) to d) before feeding the liquid into the cartridge as recited in claim 1.

b. Examiner's Reasoning for Determining Prima Facie <u>Obviousness Is Incorrect</u>

On page 3 of the Office Action, the Examiner alleged that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Fetner to

heat a sample prior to passing the sample through a cartridge because sample uptake on the sorbent is increased with sample temperature. This is incorrect. The Examiner goes on to allege that it would have been obvious to one of ordinary skill in the art to recognize that if a sample is heated then passed through a cartridge, the cartridge temperature will increase to the temperature of the liquid that is passing therethrough. This alleged "common sense" principal provides no reason for one to have applied such procedure to a solid phase extraction process as claimed.

Appellants submit that it would not have been obvious to one of ordinary skill in the art to have modified Fetner with Peterson to heat a sample prior to passing the sample through a cartridge on the alleged grounds that sample uptake on the sorbent is increased with sample temperature. The Examiner's statement is based on a clear misunderstanding of the present process and the process of Peterson. In fact, sample uptake on the sorbent in the present process actually is decreased with increasing temperature, thus making the Examiner's alleged reason to have combined the references incorrect.

Peterson discloses a chemical process in which the reaction efficiency of an effluent (reaction mixture) is enhanced by increasing the temperature of the effluent (reaction mixture) downstream from the column and adding residence time or reaction time for slow reaction mixtures.

In contrast, the present specification and claims are related to absorption in a solid phase extraction, which is not a chemical process as in Peterson but is instead a physical process in which sample uptake at the sorbent (absorption) is decreased with increasing of sample temperature.

Moreover, the chemical process in Peterson has no relationship, in any manner, to the physical process of a solid phase extraction as set forth in the present specification and claims. One would not have found Peterson's description of a chemical process to provide

any reason to modify a different physical process in which temperature control effects very different (and unrelated) results.

Thus, the Examiner's reasoning that it would have been obvious to one of ordinary skill in the art to have modified Fetner with Peterson to heat a sample prior to passing the sample through a cartridge because sample uptake on the sorbent is increased with sample temperature is incorrect, and provides no proper reason for the combination to have been made.

Regarding to Examiner's allegation that it is well known in the art (e.g., common sense) that a heated liquid would increase the temperature of a device through which the liquid is passed also provides no reason for one to have applied any such alleged common sense to a solid phase extraction process as claimed.

That is, even if one of ordinary skill in the art did know that passing a heated liquid through a device may heat the device to some extent, the fact remains that (1) the Examiner has failed to cite any reference providing any description of a use of this technique to heat a process device, and (2) such generality alone provides no reason for one to have applied such theory/knowledge to the claimed solid phase extraction process. There is thus nothing to have directed one to the present process for any possible beneficial result relevant to solid phase extraction.

For all the foregoing reasons, Appellants submit that the Examiner's reasoning for determining prima facia obviousness is incorrect and insufficient as a matter of law. The rejection should be withdrawn for this additional reason.

B. <u>Conclusion</u>

For the foregoing reasons, Appellants submit that claims 1 and 3-7 are patentable over Fetner and Peterson, taken alone or in combination.

VIII. CONCLUSION

For all of the reasons discussed above, it is respectfully submitted that the rejection is in error. For all of the above reasons, Appellants respectfully request this Honorable Board to reverse the rejection of claims 1 and 3-7.

Respectfully submitted,

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APPENDIX A - CLAIMS APPENDIX

CLAIMS INVOLVED IN THE APPEAL:

1. Solid phase extraction process for extracting an analyte from a sample comprising one or more of the following steps:

a) conditioning a sorbent in a cartridge by passing a liquid suitable for conditioning through the cartridge;

b) applying a sample that contains the analyte to the sorbent by passing a liquid which contains the sample through the cartridge;

c) washing the sorbent by passing a wash liquid through the cartridge;

d) eluting the analyte from the sorbent by passing an elution liquid through the cartridge,

wherein the temperature of the cartridge is raised or lowered to a predetermined value during one or more of the steps a) to d), and

wherein the temperature of the cartridge is raised or lowered by heating or cooling one or more of the liquids used in step a) to d) before feeding to the cartridge.

3. Solid phase extraction process according to Claim 1, wherein the temperature of the cartridge is raised or lowered in step a), preferably by heating or cooling the liquid for conditioning of the sorbent.

4. Solid phase extraction process according to Claim 1, wherein the temperature of the cartridge is raised or lowered in step b), preferably by heating or cooling the liquid which contains the sample.

5. Solid phase extraction process according to Claim 1, wherein the temperature of the cartridge is raised or lowered in step c), preferably by heating or cooling the wash liquid.

6. Solid phase extraction process according to Claim 1, wherein the temperature of the cartridge is raised or lowered in step d), preferably by heating or cooling the elution liquid.

7. Solid phase extraction according to Claim 1 which also comprises the step of drying the cartridge, before or after one or more of the steps a) to d), drying being carried out by passing a suitable gas through the cartridge, wherein the gas is heated prior to feeding to the cartridge.

APPENDIX B - EVIDENCE APPENDIX

NONE

APPENDIX C - RELATED PROCEEDINGS APPENDIX

NONE